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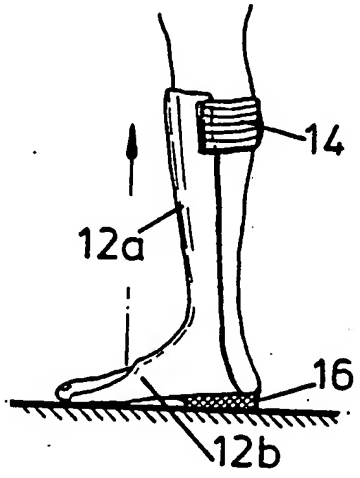
(54) Title: IMPROVED ANTERIOR FLOOR-REACTION TYPE ANKLE-FOOT ORTHOSIS



(57) Abstract

An interior moulded floor-reaction (FR) ankle-foot (AFO) (10) is described which has a fixed ankle angle and a detachable heel wedge (16) which allows the vertical alignment of the brace to be adjusted. The anterior leg portion (12a) has an elastic calf strap (14) for controlling plantar flexion. The AFO is moulded in a single piece of plastic with the leg portion (12a) being integral with the foot portion (12b) and the elastic strap (14) passes around the back of the calf. The FR AFO fits inside the patient's shoe.

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IMPROVED ANTERIOR FLOOR-REACTION TYPE ANKLE-FOOT ORTHOSIS

The present invention relates to floor-reaction type ankle-foot orthosis.

An anterior floor-reaction orthosis (AFRO) is a brace that prevents the ankle joint from dorsiflexing. In the case of a paralysed limb, without any brace, the ground reaction vector passes through the ankle joint because no torque can be transmitted. However, with an AFRO, the base of the ground reaction vector can be moved forward to the metatarsal region of the foot as shown in Fig. 1a. In this position the ground reaction vector acts ahead of the anatomical knee joint axis and thus stabilises the knee in extension without muscular action.

Traditionally, a paralysed leg is braced using a knee-ankle-foot orthosis (KAFO) that incorporates a mechanically lockable joint positioned at the side of the anatomical knee. In contrast, the anterior floor-reaction orthosis (AFRO) principle may be used to stabilise the paralysed leg without physically locking the knee in extension. This has the major advantage that during the swing phase of walking the knee can flex to gain ground clearance. In addition, this provides improved cosmesis and reduces weight and cumbrance. However, the AFRO only stabilises the knee on the condition that the ground reaction vector is ahead of the

knee axis as shown in Fig. 1a. If the ground reaction vector should shift behind the knee as shown in Fig. 1b, then the knee would buckle and the leg would collapse if there were no knee extensor muscle action. Thus, the AFRO is only used or prescribed when the patient has sufficient control of his knee extensor musculature to avoid collapse in these situations. Alternatively, paralysed muscles may be electrically activated in response to such an incident as disclosed in U.S. Patent No. 5,121,747.

An object of the present invention is to provide an improved floor-reaction orthosis which obviates or mitigates at least one of the aforementioned disadvantages.

This is achieved by providing a moulded plastic orthosis shell formed to be in close approximation to the anatomical limb. The leg portion of the plastic shell includes an elastic calf strap for controlling plantarflexion and a detachable heel wedge is provided which allows the vertical alignment of the brace to be adjusted. The improved foot-ankle orthosis fits inside the patient's shoe.

In one arrangement the floor-reaction orthosis is moulded in a single piece of plastic with the leg portion being integral with foot portion and the elastic strap is fastened to the top of the leg portion and passes round the back of the calf. The brace is fabricated such that the foot portion is made in one angled position which is

typically 10° plantarflexion. This allows various heel wedges to be inserted beneath the heel to allow correct vertical alignment of the subject in the brace so that the correct ground reaction vector position is achieved. This permits accommodation of variations presented by different shoe heel heights.

The device is straightforward to fabricate and uses a thermoformed plastic sheet or fibre composite laminate which is made by thermoforming the plastic sheet over a plaster of paris mould of the patient's leg.

According to one aspect of the present invention, there is provided a floor-reaction orthosis comprising a below-knee moulded orthosis shell proportioned and dimensioned to be in close proximity to the anatomical limbs, said shell having a leg portion and a foot portion, said leg portion fitting over the anterior surface of the limb, and the foot portion being coupled to the leg portion to wrap around the foot, said leg portion having an elastic strap coupled thereto for fitting around the calf of the limb, said shell being moulded for a single ankle position of plantarflexion, said foot portion being adapted to receive separate heel means for providing, in use, correct vertical alignment of the subject in the orthosis whereby the correct ground reaction vector position is achieved.

The leg and foot portion are integrally moulded and fabrication is achieved by thermoforming a plastic sheet

over a plaster of paris cast of the patient's leg. The orthosis may be moulded in a specific angle of plantarflexion depending on the requirements of a particular patient and the elastic strap can be fixed to the anterior surface of the orthosis by a number of ways, for example, slots may be moulded in the anterior surface and the strap passed therethrough or else the strap may be secured to the orthosis by fastening means, such as rivets and the like.

According to another aspect of the present invention there is provided a floor-reaction orthosis comprising a moulded anterior limb portion integral with a foot portion, the limb portion having an elastic strap coupled thereto for fitting around the calf of the limb, and the moulded portion being mould to a specific angle of plantarflexion for accommodating heel wedges to provide correct vertical alignment of the subject in the orthosis.

These and other aspects of the present invention will become apparent from the following description when taken in combination with the accompanying drawings in which:-

Fig. 2 is a perspective view of an embodiment of a floor-reaction orthosis (FRO) in accordance with the present invention;

Fig. 3 is a side view of a limb fitted with the floor-reaction orthosis shown in Fig. 2 with an adjustable heel wedge;

Figs. 4a and 4b depict how the control of

plantarflexion is achieved with the FRO by means of the elastic strap.

Reference is first made to Fig. 2 of the drawings which depicts a floor-reaction orthosis generally indicated by reference numeral 10 which consists of a plastic moulded shell 12 which is formed to fit the front of the calf and the foot of the patient and which has an elastic strap 14 attached thereto for securing the anterior shell portion 12a to the patient's leg. The plastic shell is fabricated from thermoformed plastic sheet or fibre composite laminates by thermoforming the sheet over a plaster of paris mould of the patient's leg. As best seen in Fig. 3, the orthosis shell 12 is fabricated in a single angle position such that when fitted to the subject as shown in Fig. 3, there is a space between the heel of the subject and the floor. This allows a plastic heel wedge 16 to be inserted at the heel to allow the correct vertical alignment of the subject in the brace so that the correct ground reaction vector (GRV) position is achieved; this means that the GRV passes in front of the keen as shown in Fig. 3. The angle of fabrication is typically 10° of plantarflexion and can accommodate variations presented by different shoe heel heights.

Reference is now made to Figs. 4a and 4b of the drawings which depicts the control of plantarflexion by means of the elastic strap 14. The elastic strap 14

stretches to provide plantarflexing control during the foot contact to foot-flat phase of early stance phase as indicated in Figs. 4a and 4b respectively. The traditional ankle-foot orthosis immobilises plantarflexion and produces an unnatural gait similar to walking in rigid boots, for example, ski boots. With the present floor-reaction orthosis natural gait is facilitated because a natural rollover is provided similar to normal walking. At heel contact as shown in Fig. 4a, the heel portion 16 contacts the ground first and as forward movement occurs the orthosis leads the leg by virtue of the elastic strap 14 mimicing natural rollover and as the forward motion of the subject continues, the orthosis is retained on the leg as shown in Fig. 3.

The embodiment hereinbefore described provides a number of advantages over the prior art devices. Because the orthosis is moulded in a single piece, ankle joint components are not required and it is straightforward to fabricate the shell using thermoformed plastic sheet or fibre composite laminates. In addition, with the new floor-reaction orthosis for a given thickness of plastic material, the new shell is stiffer in resisting dorsiflexion. This allows thinner section materials to be used which in turn allows a shoe size closer to, or the same as, the patient's to be used. In a traditional ankle-foot orthosis it is usually necessary to go up at least one shoe size to accommodate the orthosis thereby

adding unnecessary weight and foot length that adversely affects ground clearance during swing phase. With present orthosis no extra foot length is required facilitating natural rollover and providing cosmesis which is also important.

The elastic strap provides plantarflexion control during the foot contact to foot-flat phase of early stance phase as hereinbefore described whereas the traditional ankle-foot orthosis immobilises plantarflexion and produces an unnatural gait similar to walking in rigid boots. The plastic heel wedge allows the correct vertical alignment of the subject in the brace so that the correct ground reaction vector position is achieved. This allows the brace to be fabricated with one ankle position which is typically 10^{o} plantarflexion, but accommodates variations presented by the different shoe heel heights.

It will also be understood that the floor-reaction orthosis hereinbefore described could be used in combination with a functional electrical stimulation system, such as disclosed in U.S. Patent No. 5,121,747 or could be used by itself.

CLAIMS

1. A floor-reaction orthosis comprising a below-knee moulded orthosis shell proportioned and dimensioned to be in close proximity to the anatomical limbs, said shell having a leg portion and a foot portion, said leg portion fitting over the anterior surface of the limb, and the foot portion being coupled to the leg portion to wrap around the foot, said leg portion having an elastic strap coupled thereto for fitting around the calf of the limb, said shell being moulded for a single ankle position of plantarflexion, said foot portion being adapted to receive separate heel means for providing, in use, correct vertical alignment of the subject in the orthosis whereby the correct ground reaction vector position is achieved.

2. A floor-reaction orthosis as claimed in claim 1 wherein the leg and foot portion are integrally moulded and fabrication is achieved by thermoforming a plastic sheet over a plaster of paris cast of the patient's leg.

3. A floor-reaction orthosis as claimed in claim 1 or claim 2 wherein the orthosis is moulded in a specific angle of plantarflexion.

4. A floor-reaction orthosis as claimed in claim 3 wherein the specific angle is about 10^{o} plantarflexion.

5. A floor-reaction orthosis as claimed in any preceding claim wherein the separate heel means is a wedge-shaped

element.

6. A floor-reaction orthosis as claimed in any preceding claim wherein slots are located in the anterior surface of the orthosis and said elastic strap passes through the slots.

7. A floor-reaction orthosis as claimed in any one of claims 1 to 5 wherein the elastic strap is secured to said anterior surface of the orthosis by rivets.

8. A floor-reaction orthosis comprising a moulded anterior limb portion integral with a foot portion, the limb portion having an elastic strap coupled thereto for fitting around the calf of the limb, and the moulded portion being mould to a specific angle of plantarflexion for accommodating heel wedges to provide correct vertical alignment of the subject in the orthosis.

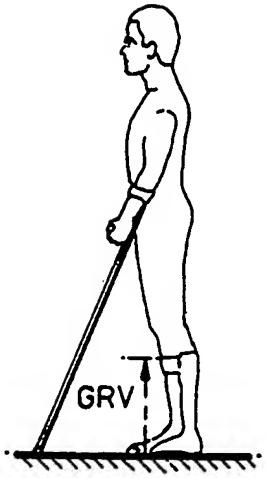

FIG.1a

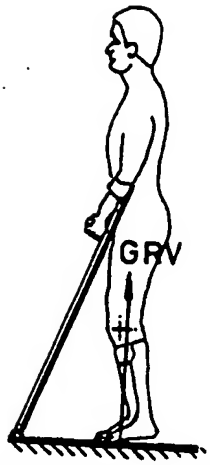

FIG.1b

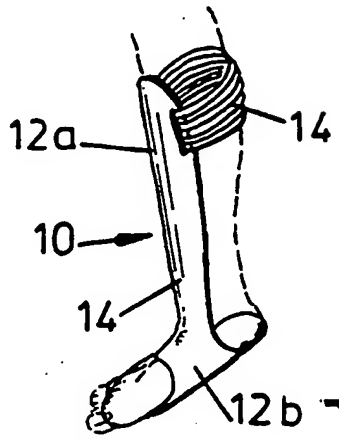

FIG.2

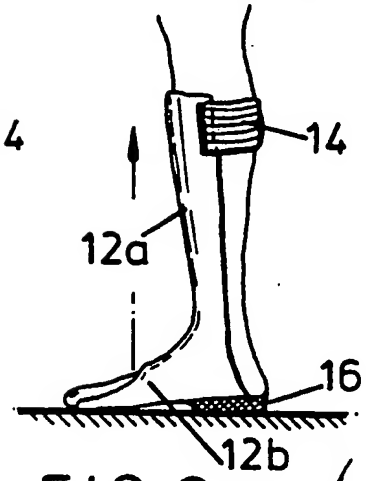

FIG.3

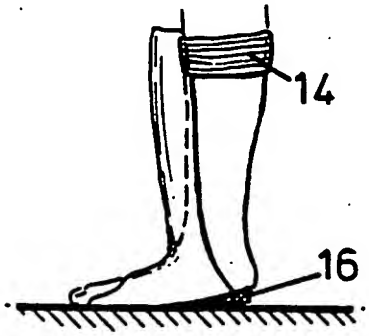

FIG.4a

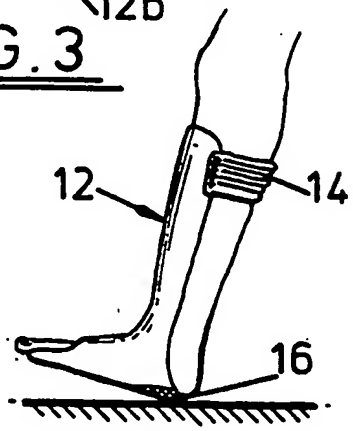

FIG.4b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 93/01354

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61F 5/04, A61F 5/37
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	US, A, 4862900 (WILHELM J. HEFELE), 5 Sept 1989 (05.09.89), column 3, line 4 - line 43, figure 1 --	1-3,8
A	US, A, 4559934 (PHILIPP), 24 December 1985 (24.12.85), column 2, line 43 - line 55 --	1,8
A	EP, A1, 0372452 (BAUERFEIND GMBH & CO.), 13 June 1990 (13.06.90), column 3, line 22 - column 4, line 9, figures 1,2 --	1-2,6-8

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 3504668 (R.E. BOUDON), 7 April 1970 (07.04.70), column 3, line 73 - column 4, line 14, figure 3 --	1-2,8
A	US, A, 4774936 (MEOLA NEE VANNINI), 4 October 1988 (04.10.88), column 3, line 27 - line 44, figure 2 --	1-4,8

S/ 5793

INTERNATIONAL SEARCH REPORT

Information on patent family members

30/07/93

International application No.
PCT/GB 93/01354

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		EP-A,B- 0269946	08/06/88
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